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10/659,970	09/11/2003	Beth A. Lange	KCC 4973 (K-C 17,890)	5030
45736	7590	07/24/2008	EXAMINER	
Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102				CLAYTOR, DEIRDRE RENEE
ART UNIT		PAPER NUMBER		
			1617	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/659,970	LANGE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 April 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-9,11,12,14-22,24,25 and 27-51 is/are pending in the application.  
 4a) Of the above claim(s) 31-48 and 50 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 3-9, 11-12, 14-22, 24-25, 27-30, 49, 51 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

Applicants remarks filed on 4/14/2008 have been fully considered. In particular, Applicants argue over the 35 USC 103 rejections that Fox fails to disclose a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material and a solidifying agent selected from the group listed in claims 1, 19, 49 and 51. Applicants argue that Fox teach lower percentages of the water-soluble film forming polymeric materials than the present application. Applicants further argue that Akihiro et al. does not teach that the pack material needs to be a water-soluble material capable of solubilizing on the skin in no more than about 50 seconds. Applicants further argue that Kyoko (Watanabe) does not fulfill the deficiencies. To summarize, Applicants argue that none of the references teach a film product comprising 40% by weight to about 70% be weight of a water-soluble film forming polymeric material, the solidifying agents listed in claims 1, 19, 49 and 51 or that the film product dissolves on the lips in no more than about 50 seconds.

In response to the above arguments, it is noted by the Examiner as well as the Applicant, that Fox teaches that the compositions comprise from about 0.75-5% by weight of a water soluble film forming polymer and from about 6.5-23% by weight of a polyvinyl alcohol which is considered a water soluble film forming polymer as taught by Applicants. The maximum amount of the water-soluble film forming polymeric material taught by Fox is 28% by weight which is not too far removed from the 40% claimed in the instant invention, absent a showing of unexpected results. Because the claimed invention and the Fox reference used in the rejection are comprised of the same

components that are useful in personal care products, it would be obvious to vary and/or optimize the amount of the water soluble polymer provided in the composition to provide the desired skin treatment properties. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937) and In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Further, claim 51 is now amended to include particular solidifying agents and due to the amendment, a modified rejection is given below.

In regards to the limitation of the composition being capable of substantially dissolving on the lips in no more than about 50 seconds, this is considered a property of the water-soluble film forming polymer. Therefore, because the reference teaches the exact polymers as presently claimed, it would be obvious that the polymer will perform the same function because “dissolving on the lips in no more than about 50 seconds” is an inherent property of the polymer. The Akhiro and Kyoko references were used to fill in the other deficiencies.

Applicants argue that Akhiro does not teach that their pack material is a water soluble material or that the pack material is substantially dissolvable on lips in no more than about 50 seconds. It is argued that the gel must be removed from the surface of the skin after a short period of time and that the material is multi-layered. In response to these arguments, the Akhiro reference was used to teach that lip treatments comprised of humectants provide moisturization to the lips, which further addresses the limitation of a composition that contains a humectant being beneficial as a lip treatment. Akhiro also teaches that lip treatment sheets can be sized and configured to fit the lips. It

would be obvious to combine the teachings of Akhiro with the teachings of Fox because Fox teaches sheets that are capable of delivering skin care ingredients such as humectants to the skin and Akhiro teaches that the lips are known to be treated via application of sheet-type compositions, such those sheet-type compositions that deliver humectants to moisturize the lips. Therefore, the Akhiro reference was used to teach the use of lip treatments in the form of sheet-type compositions.

Applicants argue the Kyoko does not teach the 40-70% by weight of the water-soluble film forming polymeric material and does not teach that the skin fill is capable of substantially dissolving on lips in no more than about 50 seconds and that the film must be peeled off. The Kyoko reference is comprised of the same ingredients as those claimed, including the solidifying agent, and it is also used in a lip treatment. Because the compositions of Kyoko have the same ingredients as the present invention, absent a showing of unexpected results, it would be obvious to vary and/or optimize the amount of the water-soluble polymer provided in the composition to provide the desired skin treatment properties. Further, one would determine that the composition is capable of dissolving on the lips in no more than about 50 seconds as claimed, because Kyoko is comprised of the same exact polymers and as discussed above, this is an inherent property of the polymers.

Applicant's arguments against the 35 USC 103(a) rejection over Fox in view of Akhiro, Kyoko and further in view of Yang et al. have been considered. The same arguments are set forth for the Fox, Akhiro and Kyoko references; therefore, please refer to the response to those arguments set forth above. Applicants argue that Yang

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does not teach a film product that is capable of substantially dissolving on lips in no more than about 50 seconds or teach a delivery system that can treat and moisturize lips. Applicants also argue that Yang teach a multi-layered system. This argument is not found persuasive because as pointed out in the previous Office Action, Yang teaches that not only is the film ingestible, but that it is also capable of delivering pharmaceutical, cosmetic or biologically active agents. Further Yang teaches that pullulan is a water-soluble polymer suitable for forming water soluble and dissolvable films and/or sheets for the delivery of cosmetic and/or pharmaceutical agents. Further, Yang et al. was used to teach that pullulan is a water-soluble polymer that is suitable for forming water soluble and dissolvable films and/or sheets for the delivery of cosmetic and/or pharmaceutical agents. The reference was not used to teach any form of layering.

Due to Applicants amendments, please see the modified rejections given below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0071755 to Priscilla S. Fox, published April 15, 2004 in view of JP 61-176512 to Watanabe, published August 8, 1986.

Fox teaches a composition in the form of a water soluble sheet for use in the personal care field (see abstract, in particular). Fox teaches that the sheets comprise a base composition including a water soluble film forming polymer and a humectant (moisturizing agent), and can also comprise skin care ingredients (see abstract, in particular). Fox teaches that the water soluble film releases the skin care ingredients upon exposure to sufficient moisture (see paragraph 0005, in particular). Accordingly, it is considered that Fox teaches a single layer film having a water-soluble film-forming polymeric material and a moisturizing agent (humectant) as recited in the claim.

Fox does not specifically exemplify a composition having the recited components in the specific weight percentages as claimed or the specific solidifying agents as listed in the claims.

Watanabe teaches that drying and chapping of the lips can be treated by providing to the lips a humectant and an oleaginous wax that is effective to supply the skin with moderate oiliness, such as olive oil and lanolin (an animal wax) (see abstract, in particular), and thus teaches the solidifying agents as recited in claim 51.

Fox teaches a general range that is suitable for the water-soluble polymer in the "base composition." It is furthermore noted that Fox teaches that the water-soluble polymer is included in the composition at 0.75-5% by weight and they also teach that polyvinyl alcohol (another water soluble polymer) is present from about 6.5-23% by weight. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the water-soluble polymers provided in the composition, according to the guidance provided by Fox, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Fox et al. does teach that the composition contains from 0.75% to 12% by weight of the humectant (moisturizing agent) (see paragraph 0009, in

particular), and between 2% to 22% by weight of the soap (solidifying agent) (see paragraph 0033, in particular), which are amounts that meet and/or overlap with the ranges as claimed.

Accordingly, it is considered that one of ordinary skill in the art at the time of the invention was made would have found it obvious to provide the water soluble skin care sheet of Fox in a form that is sized and configured for application to the body because Fox teaches that sheets are capable of delivering skin care ingredients to the skin with the teachings of Watanabe which teaches providing animal waxes such as lanolin to cosmetic compositions for application to the lips. One would be motivated to add an animal wax such as lanolin in an effort to prevent drying and chapping of the skin (lips).

Claims 1, 3-9, 11-12, 14-18 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0071755 to Priscilla S. Fox, published April 15, 2004, in view of JP 11-209222 to Akihiro et al, published August 3, 1999, and further in view of JP 61-176512 to Watanabe, published August 8, 1986.

Fox teaches a composition in the form of a water soluble sheet for use in the personal care field (see abstract, in particular). Fox teaches that the sheets comprise a base composition including a water soluble film forming polymer and a humectant (moisturizing agent), and can also comprise skin care ingredients (see abstract, in

particular). Fox teaches that the water soluble film releases the skin care ingredients upon exposure to sufficient moisture (see paragraph 0005, in particular). Accordingly, it is considered that Fox teaches a single layer film having a water-soluble film-forming polymeric material and a moisturizing agent (humectant) as recited in the claim.

Regarding the amounts of each component provided, Fox et al. teaches that the composition can contain from 0.75-5% by weight of the water soluble polymer and 6.5-23% by weight of polyvinyl alcohol (also a water soluble polymer), from 0.75% to 12% by weight of the humectant (moisturizing agent), which are amounts that meet and/or overlap with the ranges as claimed. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the ingredients provided in the composition, according to the guidance provided by Fox, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the claim recitation that the "single-use lip treatment product is a film that is capable of substantially dissolving on lips in no more than about 50 seconds....", it is recognized that because the prior art teaches the exact water soluble polymers as the instant application, it would obviously perform the same function of dissolving in no

more than about 50 seconds because this is considered a property of the polymer. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Fox does not specifically teach that the product is sized and configured for application to the lips, as recited in claim 1. Fox also does not specifically teach providing a “solidifying agent” such as one of those recited in claim 1 that is suitable for lip care treatment in particular.

Akihiro et al. teaches that a sheet-like humectant pack can be provided for the treatment of lips (see abstract, in particular), and especially to moisturize dry lips by providing a humectant (see abstract and paragraph 0001, in particular). Akihiro et al. teaches that sheets for application to the lips can be sized and configured to fit the lips (see paragraph 0020, in particular).

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the water soluble skin care sheet of Fox in a form that is sized and configured for application to lips, as in the sheet taught by Akihiro et al, because Fox teaches that sheets are capable of delivering skin care ingredients such as humectants and emollients to skin, whereas Akihiro et al. teaches that the lips are a part of the skin that it is known can be treated via application of sheet-type compositions, such as sheet compositions that deliver humectants to

moisturize the lips, and that it is also known to size and configure such sheet compositions for lip application. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the skin care sheet of Fox in a size and configuration suitable for application to lips, with the expectation of providing a sheet composition capable of imparting cosmetic benefits, such as moisturizing benefits, to the lips.

Fox and Akihiro et al. do not specifically teach providing a “solidifying agent” in the lip care composition, such as one of those recited in claims 1, 19 and 49.

Watanabe teaches that drying and chapping of the lips can be treated by providing to the lips a humectant and an oleaginous wax that is effective to supply the skin with moderate oiliness, such as olive oil and lanolin (an animal wax) (see abstract, in particular), and thus teaches the solidifying agents as recited in claims 1, 19 and 49.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the oleaginous wax of Watanabe in the lip treatment composition of Fox and Akihiro et al, because Fox and Akihiro et al. teach that lips can be treated to moisturize with the treatment sheets, and that such sheets can contain treatment actives such as moisturizers and humectants, and Watanabe teaches that oleaginous waxes can be provided to treat dry and chapped lips. Thus, it is considered that one of ordinary skill in the art would have found it

obvious to provide the oleaginous waxes as a skin care additive in the lip treatment sheets of Fox and Akihiro et al, with the expectation of providing a suitable skin care active capable of moisturizing and treating dry lips.

Regarding the amount of oleaginous wax provided, it is noted that Fox teaches that up to 50% by weight of the base composition can be added skin feel ingredients such as the humectants and moisturizers (see paragraphs 0037-0039, in particular), which is an amount that meets and/or overlaps with that claimed. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the oleaginous wax provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claim 3, it is noted, as discussed above, that Fox teaches a general range that is suitable for the water-soluble polymer in the "base composition." It is furthermore noted that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each of the components, such as the water-soluble film

forming product due to the loss of water in the drying process. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the water-soluble polymer provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claim 4, Fox teaches that the water-soluble film forming polymeric material can be polyvinylpyrrolidone (see paragraph 0010, in particular), as recited in the claim.

Regarding claim 5, Fox teaches that the humectant can be present in an amount of from 0.75% to 12% (see paragraph 0009, in particular), which is an amount that meets and/or overlaps with that claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of humectant provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 6-7, Fox teaches that a preferred humectant is propylene glycol (see paragraph 0009, in particular), and can also include other humectants such as glycerin (see paragraph 0012, in particular), as recited in the claims.

Regarding claims 8-9, Fox teaches that other skin conditioning agents added to the composition can include petrolatum (see paragraph 0038, in particular), and thus teaches providing the occlusive-type moisturizing agent as claimed.

Regarding claims 11-12, it is noted that Fox teaches various methods of forming the sheet (see paragraphs 0014-0017, in particular) and also teaches that different amounts of the ingredients, such as the magnesium aluminum silicate, can result in more viscous base compositions that affect the thickness of the resulting sheet product (see paragraph 0009, in particular). Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ingredients such as the magnesium aluminum silicate provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a sheet composition having desired properties, such as a desired thickness. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the length of the product as recited in claim 17, it is noted that Fox, Akihiro et al. and Watanabe render obvious shaping and configuring the composition for application to lips, as discussed above. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious based on the teachings of these references to provide a length of the sheet that is suitable to fit on at least a portion of the lips, such as a length of no more than about 8 centimeters, with the expectation of providing a suitable treatment composition for the lips.

Regarding claim 18, Fox teaches that the composition can contain aloe, vitamin E acetate, and others (see paragraph 0038, in particular), as well as antibacterial agents (see paragraph 0046, in particular), and thus teaches providing pharmaceutically acceptable agents and antimicrobials, as recited in the claim.

Regarding claim 49, Fox and Akihiro et al. render obvious a single-use lip treatment that is sized and configured for application to the lips, and that contains the water-soluble film forming polymeric material, the moisturizing agent and solidifying agent in the amounts as claimed, as has been discussed for claim 1 above. Fox furthermore teaches that the composition can contain the vinyl polymer that is polyvinyl alcohol (see paragraph 0009, in particular), which is a water-dispersible polymer as

indicated by Applicants on page 8 of the Specification. Fox teaches that the polyvinyl alcohol can be provided in an amount of from about 6.5% to about 23% by weight of the composition (see paragraph 0009, in particular), which is an amount that meets and/or overlaps with the amount recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the polyvinyl alcohol provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties, such as desired skin benefit delivering properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 19-22, 24-25 and 27-30 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0071755 to Priscilla S. Fox, published April 15, 2004, in view of JP 11-209222 to Akihiro et al, published August 3, 1999 and JP 61-176512 to Watanabe, published August 8, 1986, and further in view of WO 03/030881 A1 to Yang et al, published April 17, 2003.

Fox, Akihiro et al. and Watanabe are applied as discussed for claim 1 above, and render obvious a dissolving lip moisturizing product comprising a water-soluble polymer, a humectant that can comprise glycerin, and a solidifying agent that can be an

oleaginous wax, in the amounts as claimed, and that is sized and configured for application to lips.

Fox, Akihiro et al. and Watanabe do not specifically teach that the dissolvable product contains pullulan, as required by claim 19. However, Fox teaches that the base composition for the film is made up of a water soluble polymer and polyvinyl alcohol (see paragraph 0009, in particular).

Yang teaches water-soluble delivery systems in the form of a film and comprising a glucan (see abstract, in particular). Yang teaches that the film is ingestible, but that it is also capable of delivering pharmaceutical, cosmetic or biologically active agents (see abstract, in particular). Yang teaches that the polymer pullulan is the preferred glucan, because of its high water solubility (see pages 1, 3 and 5), and thus teaches that pullulan is a water-soluble polymer suitable for forming water soluble and dissolvable films and/or sheets for the delivery of cosmetic and/or pharmaceutical agents. Yang et al. also teaches that the pullulan can be suitably used in combination with other polymeric materials to form the film, such as polyvinyl alcohol (see page 5, lines 20-35, in particular).

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the pullulan of Yang in the dissolving sheet composition of Fox, Akihiro and Watanabe, because Fox, Akihiro and

Watanabe teach the dissolving sheet comprises a water soluble polymer, and Yang teaches that pullulan is a water soluble polymer that can be advantageously used in dissolving film preparations, and that is also suitably used in combination with polyvinyl alcohol, as taught by Fox, Akihiro et al. and Watanabe. Thus, one of ordinary skill in the art would have been motivated provide pullulan as the water soluble polymer in the sheet preparation of Fox, Akihiro et al. and Watanabe, with the expectation of providing a polymer that is suitable for forming the dissolving sheet compositions, and that can also be suitably combined with polyvinyl alcohol for forming such compositions. Accordingly, claim 19 is considered to be obvious over the teachings of Fox, Akihiro et al, Watanabe and Yang et al.

Regarding the amounts of pullulan and glycerin each component provided, as recited in claims 20-22, Fox et al. teaches that the composition can contain from 0.75-5% by weight of the water soluble polymer, and from 0.75% to 12% by weight of the humectant (moisturizing agent), which are amounts that meet and/or overlap with the ranges as claimed. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the ingredients provided in the composition, according to the guidance provided by Fox, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claim 23, Watanabe teaches providing an oleaginous wax that is effective to supply the skin with moderate oiliness, such as olive oil and lanolin (an animal wax) (see abstract, in particular), as has been discussed for claim 1 above, and thus teaches the solidifying agents as recited in claim 23.

Regarding claims 24-25, it is noted that Fox teaches various methods of forming the sheet (see paragraphs 0014-0017, in particular) and also teaches that different amounts of the ingredients, such as the magnesium aluminum silicate, can result in more viscous base compositions that affect the thickness of the resulting sheet product (see paragraph 0009, in particular). Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ingredients such as the magnesium aluminum silicate provided in the composition, according to the guidance provided by Fox, Akihiro et al, Watanabe and Yang, to provide a sheet composition having desired properties, such as a desired thickness. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the length of the product as recited in claim 29, it is noted that Fox, Akihiro et al, Watanabe and Yang render obvious shaping and configuring the composition for application to lips, as discussed above. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious based on the teachings of these references to provide a length of the sheet that is suitable to fit on at least a portion of the lips, such as a length of no more than about 8 centimeters, with the expectation of providing a suitable treatment composition for the lips.

Regarding claim 30, Fox teaches that the composition can contain aloe, vitamin E acetate, and others (see paragraph 0038, in particular), as well as antibacterial agents (see paragraph 0046, in particular), and thus teaches providing pharmaceutically acceptable agents and antimicrobials, as recited in the claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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